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NOTICE OF ALLOWANCE AND FEE(S) DUE

7590

08/13/2002

Marla J. Mathias Bristol-Myers Squibb Company Patent Department P.O. Box 4000 Princeton, NJ 08543-4000 EXAMINER

KHARE, DEVESH

ART UNIT CLASS-SUBCLASS

1623 514-034000

DATE MAILED: 08/13/2002

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,953	09/18/2001	Giorgio Minotti	LD0226(NP)	8528

TITLE OF INVENTION: METHOD FOR REDUCING TOXICITY OF COMBINED CHEMOTHERAPIES

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1280	\$300	\$1580	11/13/2002

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. <u>PROSECUTION ON THE MERITS IS CLOSED.</u> THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above. If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is changed, pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above and notify the United States Patent and Trademark Office of the change in status, or

B. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check the box below and enclose the PUBLICATION FEE and 1/2 the ISSUE FEE shown above.

Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Box ISSUE FEE

Commissioner for Patents

Washington, D.C. 20231

(703)746-4000

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 4 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for

maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Legibly mark-up with any corrections or use Block 1) Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission. 08/13/2002 Marla J. Mathias Bristol-Myers Squibb Company Certificate of Mailing or Transmission Patent Department I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Box Issue Fee address above, or being facsimile P.O. Box 4000 Princeton, NJ 08543-4000 transmitted to the USPTO, on the date indicated below. (Depositor's name (Signature (Date) APPLICATION NO. FIRST NAMED INVENTOR ATTORNEY DOCKET NO. FILING DATE CONFIRMATION NO. 09/18/2001 09/954,953 Giorgio Minotti LD0226(NP) 8528 TITLE OF INVENTION: METHOD FOR REDUCING TOXICITY OF COMBINED CHEMOTHERAPIES APPLN. TYPE SMALL ENTITY **ISSUE FEE** PUBLICATION FEE TOTAL FEE(S) DUE DATE DUE nonprovisional \$1280 \$300 \$1580 11/13/2002 **EXAMINER** ART UNIT **CLASS-SUBCLASS** KHARE, DEVESH 514-034000 1623 1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363). 2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached. single firm (having as a member a registered attorney or agent) and the names of up to 2 "Fee Address" indication (or "Fee Address" Indication form registered patent attorneys or agents. If no name PTO/SB/47; Rev 03-02 or more recent) attached. Use of a Customer is listed, no name will be printed. Number is required. 3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type) PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the USPTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment. (A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY) Please check the appropriate assignee category or categories (will not be printed on the patent) ☐ individual ☐ corporation or other private group entity ☐ government 4a. The following fee(s) are enclosed: 4b. Payment of Fee(s): ☐ A check in the amount of the fee(s) is enclosed. ☐ Issue Fee ☐ Payment by credit card. Form PTO-2038 is attached. ☐ Publication Fee ☐ The Commissioner is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number _____(enclose an extra copy of this form). ☐ Advance Order - # of Copies Commissioner for Patents is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above. (Authorized Signature) (Date) NOTE; The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office. This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.



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Marla J. Mathias			KHARE, DE	EVESH
Bristol-Myers Squ Patent Department	ibb Company		ART UNIT	PAPER NUMBER
P.O. Box 4000			1623	
Princeton, NJ 0854	3-4000		DATE MAILED: 08/13/2002	

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The patent term adjustment to date is 0 days. If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the term adjustment will be 0 days.

If a continued prosecution application (CPA) was filed in the above-identified application, the filing date that determines patent term adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) system. (http://pair.uspto.gov)



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Bristol-Myers Squ	ibb Company		<u></u>	
Patent Department	• •		ART UNIT	PAPER NUMBER
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Princeton, NJ 0854	3-4000			
UNITED STATES			DATE MAILED: 08/13/2002	

Notice of Fee Increase on October 1, 2002

If a reply to a "Notice of Allowance and Fee(s) Due" is filed in the Office on or after October 1, 2002, then the amount due may be higher than that set forth in the "Notice of Allowance and Fee(s) Due" since there will be an increase in fees effective on October 1, 2002. See Revision of Patent and Trademark Fees for Fiscal Year 2003; Notice of Proposed Rulemaking, 67 Fed. Reg. 30634, 30636 (May 7, 2002). Although a change to the amount of the publication fee is not currently proposed for October 2002, if the issue fee or publication fee is to be paid on or after October 1, 2002, applicant should check the USPTO web site for the current fees before submitting the payment. The USPTO Internet address for the fee schedule is: http://www.uspto.gov/main/howtofees.htm.

If the issue fee paid is the amount shown on the "Notice of Allowance and Fee(s) Due," but not the correct amount in view of the fee increase, a "Notice to Pay Balance of Issue Fee" will be mailed to applicant. In order to avoid processing delays associated with mailing of a "Notice to Pay Balance of Issue Fee," if the response to the Notice of Allowance and Fee(s) due form is to be filed on or after October 1, 2002 (or mailed with a certificate of mailing on or after October 1, 2002), the issue fee paid should be the fee that is required at the time the fee is paid. If the issue fee was previously paid, and the response to the "Notice of Allowance and Fee(s) Due" includes a request to apply a previously-paid issue fee to the issue fee now due, then the difference between the issue fee amount at the time the response is filed and the previously paid issue fee should be paid. See Manual of Patent Examining Procedure, Section 1308.01 (Eighth Edition, August 2001).

Effective October 1, 2002, 37 CFR 1.18 is proposed to be revised to change the patent issue fees as set forth below. As stated above, the final fees may be a different amount, and applicant should check the web site given above when paying the fee.

(a) Issue fee for issuing each original or reissue patent, except a design or plant patent:

By a small entity (Sec. 1.27(a))--\$655.00 By other than a small entity--\$1,310.00

(b) Issue fee for issuing a design patent:

By a small entity (Sec. 1.27(a))--\$235.00 By other than a small entity--\$470.00

(c) Issue fee for issuing a plant patent:

By a small entity (Sec. 1.27(a))--\$315.00

By other than a small entity--\$630.00

Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

	Application No.	Applicant(s)	-
		MINOTTI ET AL.	
e All-wahilibe	09/954,953	Art Unit	
Notice of Allowability	Examiner		
	Devesh Khare	1623	
claims being allowable, PROSECUTION ON THE MERITS Is rewith (or previously mailed), a Notice of Allowance (PTOL-8: PTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT IS THE Office or upon petition by the applicant. See 37 CFR 1.3: This communication is responsive to 07/08/02. This communication is responsive to 07/08/02. The allowed claim(s) is/are 1-17. The drawings filed on 18 September 2001 are accepted. Acknowledgment is made of a claim for foreign priority to a) □ All b) □ Some* c) □ None of the: 1. □ Certified copies of the priority documents have also as the certified copies of the priority documents have also as the certified copies of the priority documents have also as the certified copies of the priority documents have also as the certified copies of the priority documents have also as the certified copies of the priority documents have also as the certified copies of the priority documents have also as the certified copies of the priority documents have also as the certified copies of the priority documents have also as the certified copies of the priority documents have also as	bears on the cover she S (OR REMAINS) CLOS (OR REMAINS) CLOS (S) or other appropriate or RIGHTS. This application and MPEP 1308. by the Examiner. Index 35 U.S.C. § 119(a) (a) (a) (a) (a) (a) (b) (b) (b) (c) (c) (c) (c) (c) (c) (c) (c) (c) (c	pommunication will be mailed in some is subject to withdrawal from issorted in the polication No eceived in this national stage application of the provisional application of th	ication from the
 8. CORRECTED DRAWINGS must be submitted. (a) including changes required by the Notice of Draft 1) hereto or 2) to Paper No (b) including changes required by the proposed draw 	flod	which has been approved by	the Examiner.
 (b) including changes required by the proposed draw (c) including changes required by the attached Exar Identifying indicia such as the application number (see 37 of each sheet. The drawings should be filed as a separate 9. DEPOSIT OF and/or INFORMATION about the attached Examiner's comment regarding REQUIREMENT F 	CFR 1.84(c)) should be wr paper with a transmittal le	itten on the drawings in the top mar etter addressed to the Official Drafts	gin (not the back) person.
Attachment(s) 1 ☐ Notice of References Cited (PTO-892) 3 ☐ Notice of Draftperson's Patent Drawing Review (PTO-95) 5 ☐ Information Disclosure Statements (PTO-1449), Paper 7 ☐ Examiner's Comment Regarding Requirement for Dep of Biological Material	948) 4[· No 6[Notice of Informal Patent Applica Interview Summary (PTO-413), Examiner's Amendment/Comme Examiner's Statement of Reason Other	ent

Application/Control Number: 09/954,953

Art Unit: 1623

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The applicants' response received on 07/08/2002 has been entered. The applicant's response on the rejection of claims 1-13 and 17 under 35 U.S.C. 112, second paragraph and claims 1-17 under 35 U.S.C. 102(b) over Gianni and Sparano is acknowledged. The rejections of claims 1-13 and 17 under 35 U.S.C. 112, second paragraph and claims 1-17 under 35 U.S.C. 102(b) are withdrawn.

Claims 1-17 are allowed.

1. The following is an examiner's statement of reasons for allowance: The present invention is directed to the compositions and a method for the treatment of cancer comprising administration of 4-desacetyl-4-methylcarbonate taxol and doxorubicin.

Disclosure of 4-desacetyl-4-methylcarbonate taxol when used in combination with doxorubicin would eliminate the cardiotoxicity problem in the cancer treatment is not suggested anywhere in the prior art.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Art Unit: 1623

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-1235.

Devesh Khare, Ph.D., JD(3Y).

Art Unit 1623 August 9, 2002

SAMUEL ARTS
PRIMARY EXAMINER
GROUP 1/200